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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,483	12/31/2003	Michael S. Collins	0103-0050	1206
43231	7590	10/19/2006	EXAMINER	
ZIMMER TECHNOLOGY - REEVES			RAMANA, ANURADHA	
P. O. BOX 708			ART UNIT	
WARSAW, IN 46581-0708			PAPER NUMBER	

3733

DATE MAILED: 10/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/749,483

Applicant(s)

COLLINS ET AL.

Examiner

Anu Ramana

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,8-19 and 21-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17-19 and 25 is/are allowed.
- 6) ☒ Claim(s) 1,3,4,8-16 and 21-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/31/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 8-16 and 21-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 8, the functional recitation, "to space the male and female portions apart.....maintaining relationship," renders the claim and vague and indefinite. Clearly, the sleeve of Applicants' invention maintains the implant components in an assembled arrangement. It is unclear what Applicants are trying to claim by the functional recitation.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Pfaff et al. (US 6,607,560).

Pfaff et al. disclose a modular joint prosthesis having a first component 3 with a female junction element 4 and a second component 2 with a male junction element 5 receivable within the female junction element and a hollow resilient sleeve 4 that is capable of being rolled upon itself in a ring-like configuration (Figs. 1 and 2, col. 2, lines 22-30, col. 3, lines 3-14 and col. 4, lines 12-36).

Claims 8, 10, 14, 21 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by White (US 6,428,578).

White discloses a radially flexible or "stretchable" sleeve 16 for use with a modular orthopedic implant having an outer portion able to be received in a female junction element and an inner portion able to receive a male junction element wherein the sleeve has sufficient friction and resilience, i.e., means for maintaining the first and second components ((14, 30) and 10) in an assembled condition (Figs. 3-3B and 6-8, col. 1, lines 5-8, col. 4, lines 26-67, col. 5 and col. 6, lines 1-50).

The method steps of claim 21 are inherently performed when the White modular implant is assembled together.

Claims 8, 10, 13, 14, 16, 21 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Averill et al. (US 4,921,500).

Averill et al. disclose a modular orthopedic implant having a femoral stem or "first component" 10 with a male junction element 18 and a femoral head component or "second component" 20 with a female junction element 32 and an adaptor or "hollow sleeve" 40 with grooves 66 extending circumferentially around the outer surface 52 of the sleeve that maintain the first and second components in an assembled condition wherein the stem and head components are made of a biocompatible metal (Fig. 3, col. 3, lines 16-68, col. 4 and col. 5, lines 1-51).

The method steps of claim 21 are inherently performed when the Averill et al. modular implant is assembled together.

Claims 8, 10, 13-14, 16, 21 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Pratt et al. (US 5,080,679).

Pratt et al. disclose a modular orthopedic implant including: a femoral stem or "first component" 21 with a male junction element 45; a second component including a femoral head component 25 with a female junction element 37 and an acetabular component 31; and an adaptor or "hollow sleeve" 19 that maintains the first and second components in an assembled condition wherein the stem and head components are made of a biocompatible metal (Fig. 3, col. 3, lines 16-68, col. 4 and col. 5, lines 1-51).

The method steps of claim 21 are inherently performed when the Pratt et al. modular implant is assembled together.

Claims 8-11, 14, 16, 21 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Fallin (US 5,108,452).

Fallin discloses a modular orthopedic implant including: a femoral stem or "first component" 11 with a male junction element 14; a second component including a femoral head component 27 with a female junction element 28; and an adaptor or "hollow sleeve" 46 that maintains the first and second components in an assembled condition (Figs. 6 and 18, col. 1, lines 12-23, col. 3, lines 21-23, col. 6, lines 13-68, col. 7 and col. 8, lines 1-26).

Regarding claims 9 and 11, Fallin discloses that his prosthesis can be supplied in kit form with a plurality of components 11 and 27 provided in various sizes so that a hip prosthesis can be custom fitted to a particular patient by a surgeon. Components that do not fit would be provisional implant components and components that fit would be actual implant components.

The method steps of claim 21 are inherently performed when the Fallin modular implant is assembled together.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pratt et al. (US 5,080,679) in view of McLean (US 2002/0116068).

Pratt et al. disclose that component 23 can be made of any material having properties similar to titanium. Pratt et al. disclose all the elements of the claimed invention except for the use of a polymer.

McLean teaches the use of synthetic materials such as metals, ceramics or plastics to construct prosthetic components (para [0053]).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the Pratt et al. prosthetic components of metal and polymer, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over White (US 6,428,578) in view of McLean (US 2002/0116068).

White discloses all elements of the claimed invention except for a head component engageable with the tapered neck 44 of proximal body 10 and an acetabular component engageable with the head component.

The use of an acetabular prosthesis including a cup and liner fixed to a reamed acetabular surface articulating with a spherical head attached to the tapered stem of a neck component or "proximal body" for total hip arthroplasty is well known (see paras [0003] – [0007]).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a spherical head attached to stem 44 of the White prosthesis and an acetabular cup in a reamed acetabulum for articulation with the spherical head, as taught by McLean, for total hip arthroplasty in a patient.

Claims 1, 3-4 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fallin (US 5,108,452) in view of Pfaff et al. (US 6,607,560).

Fallin discloses a modular orthopedic implant including: a femoral stem or "first component" 11 with a male junction element 14; a second component including a femoral head component 27 with a female junction element 28; and an adaptor or "hollow sleeve" 46 that maintains the first and second components in an assembled condition (Figs. 6 and 18, col. 1, lines 12-23, col. 3, lines 21-23, col. 6, lines 13-68, col. 7 and col. 8, lines 1-26). Note that the various components of the Fallin are provisional in nature in that if a particular component doesn't fit properly, it can be replaced with a better fitting component.

Fallin discloses all elements of the claimed invention except for an adaptor that is capable of being rolled upon itself into a ring-like configuration.

Pfaff et al. teaches providing a coupling element or adaptor in the form of a woven fabric to influence the deformability of the coupling element (col. 2, lines 22-31).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a coupling element, as taught by Pfaff et al., in the Fallin et al. implant, in order to influence the deformability of the coupling element, to provide an improved force-fit connection between the implant components in the device of the combination of Fallin and Pfaff et al.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pfaff et al. (US 6,607,560) in view of Fallin (US 5,108,452).

Pfaff et al. disclose all the elements of the claimed invention except for providing the components in a variety of sizes in kit form so that the components can be custom fitted to a patient during the surgical procedure.

Fallin teaches providing various prosthesis components in a kit form so that a surgeon can custom fit a prosthesis to a patient (Fig. 1 and col. 1, lines 12-39).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the Pfaff et al. components in a variety of sizes, i.e., provisional components, as taught by Fallin, so that the components can be custom fitted to a patient during a surgical procedure.

Response to Arguments

Applicants' arguments submitted under "REMARKS" in the response filed on August 4, 2006 have been fully considered but they are not persuasive.

Regarding the rejections of claims 8, 10 and 14 as being anticipated by White, Figures 6-8 of White clearly show a male component, with a tapered male portion, a female component 14 having a tapered bore corresponding to the male portion and a sleeve 16 to hold the male and female components in an assembled configuration.

Applicants' arguments with respect to Averill et al. are not persuasive. Are Applicants trying to claim that the male and female components are capable of being taper locked without a sleeve? The Examiner asks why it is necessary to use a sleeve if the male and female components can be taper locked without a sleeve. It is further noted that sleeve 40 of Averill et al. is resilient, i.e., capable of withstanding shock without permanent deformation or rupture, otherwise a mallet could not be used to place the sleeve over post 18.

Applicants' arguments with respect to Pratt are not persuasive. Again, are Applicants trying to claim that the male and female components are capable of being taper locked without a sleeve? The Examiner asks why it is necessary to use a sleeve if the male and female components can be taper locked without a sleeve. It is the Examiner's position that hollow sleeve 19 is resilient, i.e., capable of withstanding shock

without permanent deformation or rupture, otherwise, how could it hold the first and second components together?

Applicants' arguments with respect to Fallin are not persuasive. Fallin discloses that an impact driver can be used to place sleeve 46 in head 27. It is the Examiner's position that sleeve 46 must be resilient, i.e., capable of withstanding shock without permanent deformation or rupture.

Allowable Subject Matter

Claims 17-19 and 25 are allowed.

Claim 22 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-

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4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR
October 11, 2006



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER